EC Certificate Full Quality Assurance System: Certificate GB20/965349

The management system of

Penlon Limited

Abingdon Science Park, Barton Lane, Abingdon, Oxfordshire, OX14 3NB, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 01 December 2020 until 13 October 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 03 January 2017
and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC 240635

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Non-sterile anaesthesia and anaesthetic equipment, insufflation equipment, patient monitoring, oxygen therapy systems and medical hose assemblies.
Oxygen therapy flowmeters & bubble humidifiers;
AVS Ventilator, AVS MRI Ventilator & Nuffield 200 Ventilator;
Anaesthesia workstations with integrated ventilator - Prima 300 range:
Prima 320 / Prima 330e / Prima 320 Advance / Prima 325/Prima 465
Anaesthesia workstation Prima 400 series:
Prima 440, Prima 445, Prima 450, Prima 451 MRI, Prima 460, Prima 465;
A200 SP Absorber & A200SP MRI Absorber for use as part of a closed breathing system for anaesthesia;
Sigma EVA Vaporizer, Sigma Delta Vaporizer & Sigma Delta MRI Vaporizer for the provision of accurate concentrations of the anaesthetic drugs into the fresh gas supply;
Penlon Oxygen Therapy Range to provide controlled flow of humidified Oxygen to be administered to a patient:
AnaVue 4000 Patient Monitor
ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)
Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12

Appendix Page to note following devices:
Class IIa devices
- **Oxygen Therapy Flowmeters & Bubble Humidifiers**
- **Medical Hose assemblies**

Class IIb devices
- **AVS Anaesthesia Ventilator and Accessories**
- **AVS MRI Anaesthesia Ventilator and Accessories**
- **Nuffield 200 Ventilator and accessories**
- **Prima 320 Anaesthetic Machine and Accessories**
- **Prima 320 Advance Anaesthetic Machine and Accessories**
- **Prima 325 Anaesthetic Machine and Accessories**
- **Prima 330e Anaesthetic Machine and Accessories**
- **Prima 450 Anaesthetic Machine and Accessories**
- **Prima 460 Anaesthetic Machine and Accessories**
- **Prima 465 Anaesthesia Machine and Accessories**
- **Prima 440 Anaesthetic Machine and Accessories**

Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

• Prima 445 Anaesthetic Machine and Accessories
• Prima 451 MRI Anaesthetic Machine and Accessories
• A200SP Absorber and Accessories
• A200SP MRI Absorber and Accessories
• Sigma Delta Vaporizers and Accessories
• Sigma Delta MRI Vaporizers and Accessories
• Sigma EVA Vaporizer
• AnaVue 4000 Patient Monitor and Accessories
•ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)
•Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12 and Accessories

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Certificate GB20/965272

The management system of

Penlon Limited

Abingdon Science Park, Barton Lane, Abingdon,
Oxfordshire, OX14 3NB, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture, Service & commissioning of Anaesthesia and Anaesthetic Equipment, suction equipment, airway management and insufflation equipment and patient monitoring equipment.

This certificate is valid from 10 September 2021 until 13 October 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 2. Certified since 19 December 2016

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421

Penlon

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	Prima 400 Series Anaesthesia Machine
Models	Prima 440 Prima 445 Prima 450 Prima 460 Prima 465 Prima 451 MRI
Classification	Class IIb, Rule 11
Conformity Assessment Route	Annex II
GMDN Code	37710
Quality Management System	ISO 13485:2016
Notified Body	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium (**ID Number:** 1639)
CE Certificate Number	GB20/965349
Start of CE Marking	2013
European Authorised Representative	Obelis s.a. Bd. Général Wahis 53, 1030-Brussels, Belgium

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices, as amended by Directive 2007/47/EC.
All supporting documentation is retained at the premises of the manufacturer.

Place and Date of Issue Abingdon, 29th July 2021

Signed by:

Mary Ryan.

SIGNATURE

Mary Ryan

PRINT NAME

Director of Innovation, Technology & Regulatory Affairs EU PRRC

POSITION